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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,343	09/04/2001	Peter Angele	24741-1526	3363

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EXAMINER
NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	16

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/857343	Angelo et al
Examiner	**Group Art Unit**
Kaft	1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 1/14 & 2/12/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Dispositi n f Claims

☒ Claim(s) 1-19 & 23-38 is/are pending in the application.

Of the above claim(s) 14-19 & 27-31 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13, 23-26 & 32-38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Applicati n Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Receipt is acknowledged of drawings filed 2/12/03

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 (filed 9/4/01)

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Acti n Summary

In a response of 1/14/03 to a restriction requirement of 12/17/02, applicants elected Group I claims 1-13, 23-26 and 32-38 without traverse.

Claims 14-19 and 27-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 of 1/14/03.

Claims examined on the merits are 1-13, 23-26 and 32-38.

Specification

The disclosure is objected to because of the following informalities: the specification fails to contain headings designating different sections.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-Reference to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.

(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

The following suggestions are made.

Page 1,

above line 7 insert --

BACKGROUND OF THE INVENTION

1. Field of the Invention

--.

Between lines 11 and 13 insert --

2. Description of the Related Art

--.

Page 2, between lines 28 and 30 insert --

SUMMARY OF THE INVENTION

--.

Page 3, between lines 11 and 13 insert --

BRIEF DESCRIPTION OF THE DRAWINGS

(Insert the description of the drawings on page 15, lines 13-30, and cancel lines 13-30 on page 15)

DETAILED DESCRIPTION OF THE INVENTION

--.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: the last two lines at the bottom of page 1 are repeated as the first two lines on page 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 23-26 and 32-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hyaluronic acid ester as required by claim 6 as the hyaluronic acid derivative and gelatin as the hydrolyzed collagen, does not reasonably provide enablement for any hyaluronic acid derivative and any hydrolyzed collagen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Different hyaluronic acid derivatives can have substantially different physical and chemical properties. Hyaluronic acid derivatives substantially different from the hyaluronic acid ester used in the working examples would not appear to provide results obtained when using the hyaluronic acid ester.

Similarly different hydrolyzed collagens can differ substantially in properties. Hydrolyzed collagen differing substantially in properties from gelatin used in the examples would not appear to provide results shown when using gelatin.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is unclear as to the relationship of the composite matrix required to the composite matrix of claims 23 and 1. Furthermore, claim 24 repeats the composite matrix composition as recited in claim 1. This is confusing since claim 24 depends on claim 23 that depends on claim 1. Claim 24 should be written in independent form, or be amended in line 2 by changing "a", first occurrence, to -- the -- and replacing the comma after "implant" with a period and canceling all of the claim after the period.

Claim 32 is unclear by reciting "optionally" in line 3. Reciting steps or conditions that do not have to be performed confuses the metes and bounds of the invention. An optional step or condition should be recited only when intended to be used such as in a dependent claim.

Reciting "types" in line 2 of claim 34 and 35 is unclear since being a "type" is relative and subjective.

Claims 34 and 35 are confusing by not having clear antecedent basis for "the connective and supportive apparatus". Additionally, the meaning and scope of "connective and supportive apparatus" is unclear. The structure of an apparatus that is connective and supportive is uncertain.

In line 3 of claim 37, "further" should be deleted since it is unclear as to purpose of "further" in the Markush group claimed. It is suggested that "further" be deleted. Additionally, requiring glycosaminoglycans is confusing since hyaluronic acid is a glycosaminoglycan, and hyaluronic acid is required in claim 1 on which claim 37 ultimately depends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 11-13, 23-25, 32-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (5,866,165), and if necessary in view of Aoyagi et al (6,423,347) and Bishop et al (5,834,232).

The claims are drawn to a porous composite matrix formed from components containing a hyaluronic acid derivative and a hydrolyzed collagen in a weight ratio of hyaluronic acid derivative to hydrolyzed collagen of 30:70 to 99:1. Also claimed is an implant containing the composite matrix, method of making implant using the composite matrix and method of generating differentiated tissue using the composite matrix

Liu et al disclose a collagen-polysaccharide matrix for bone or cartilage repair which can be seeded with chondrocytes and implanted (col 5, lines 8-15). The collagen may be Type I collagen (col 2, line 49) and the polysaccharide can be hyaluronic acid (paragraph bridging cols 2 and 3) which has been treated with an oxidizing agent to have terminal aldehyde groups (col 2, lines 61-65). Type I collagen is gelatin which is produced by the hydrolyzing collagen as is apparent from Aoyagi et al (col 4, lines 26) and Bishop et al (col 6, lines 1-5), if needed. The hyaluronic acid containing aldehyde groups is a hyaluronic acid derivative and the Type I collagen is gelatin which is a hydrolyzed collagen. The weight ratio of Type I collagen to hyaluronic acid having aldehyde groups is 99:1 to 1:99 (col 3, lines 4-5).

The matrix of Liu et al is essentially the same as the presently claimed matrix except for the claimed ratio of hyaluronic acid derivative to hydrolyzed collagen of 30:70 to 99:1.

It would have required only limited routine experimentation and been obvious to select a preferred optimum ratio range within the ratio range of 99:1 to 1:99 disclosed by Liu et al since Liu et al disclose (col 3, lines 12-27 and col 6, lines 34-40) different forms of the matrix that

can result from selecting different proportions of collagen and polysaccharide. Such optimization for preferred results is well within the ordinary skill of the art. An implant as required by claim 23, producing an implant as required by claim 24, and producing differentiated tissue as required by claims 32-36 and 38 would have been obvious since Liu et al intend the matrix to be used for implanting to produce differentiated tissue.

Claims 5-10, 26 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-4, 11-13, 23-25, 32-36 and 38 above, and further in view of Valentini et al (5,939,323).

Claims 5 and 6 require the hyaluronic acid derivative to be an ester, claims 7-10 and 26 require a pore size within a range of 10-1000, 100-350, 350-1000 or 10-100 microns, and claims 12 and 37 require the matrix to contain a biologically active compound.

Valentini et al disclose a scaffold prepared from a hyaluronic acid ester derivative (paragraph bridging cols 4 and 5) such as an ethyl or benzyl ester (col 1, lines 55-56) that can be seeded with cells and implanted. The scaffold can have a pore size of 10-1000 microns (col 2, line 58) so as to permit cells to enter the scaffold (col 3, lines 20-25), and the scaffold can contain a bioactive molecule (col 7, lines 3-5).

It would have been obvious to use as the hyaluronic acid derivative of Liu et al an ester derivative to obtain the function of the ester derivative as taught by Valentini et al for preparing a scaffold for seeding with cells and implanting. Valentini et al would have further

suggested providing a biologically active compound in the matrix of Liu et al to obtain its function, and would have further suggested a pore size in the range of 10-1000 microns from disclosing providing the scaffold with pore sizes within this range. Selecting narrower pore size ranges within the 10-1000 range would have been merely mater of individual preference and convenience.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
4/8/03